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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,281	07/28/2003	Michael P. Harrold	5010-036-01	4709

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EXAMINER	
LUDLOW, JAN M	

ART UNIT	PAPER NUMBER
1797	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/628,281	HARROLD, MICHAEL P.	
	Examiner	Art Unit	
	Jan M. Ludlow	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *7/11/2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23 and 34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23, 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1 – 23, 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hunt (U.S. Pat. Appl. No. 2002/0110495) in view of Gifford (5750335).

Regarding claims 1 and 23, Hunt teaches a method for purifying a fluid. Hunt teaches the step of providing a microfluidic purification device, e.g., sample holder 1, having an entry port 24, a purification column, e.g., column module 5 comprising cylindrical capsule 51, comprising a purification material comprising a packed bed 60 of particulate chromatography separation medium in fluidic communication with the entry port and an output port 31, and an output reservoir inside tube 8 in fluidic communication with the purification column (see paragraphs 5 – 43 and 57 – 64; figures 1 – 4). Hunt teaches that the packed bed comprising a particulate resin can

comprise various types of affinity resins for facilitating fluid sample purification (see paragraphs 65 – 87). Hunt teaches that the disclosed microfluidic device can process microliter fluid sample volumes (see paragraph 93). Hunt teaches that the fluid sample to be processed is placed in the sample chamber 22 with a diluent or binding buffer and is driven through the column 60 into tube 8 (see, e.g., paragraphs 90 – 92 and 108).

Hunt fails to teach providing and removing excess diluent prior to supplying the sample.

Gifford teaches a column for use in a centrifuge (i.e., a spin column) similar to that of Hunt. Prior to use, the spin column is washed and equilibrated in buffer (col. 28, lines 8-9).

It would have been obvious to provide and remove excess buffer in the column of Hunt in order to wash and equilibrate the column before applying the sample for use as taught by Gifford. Further, Hunt teaches that the purification column is initially saturated with diluent or binding buffer so that the material in the fluid sample to be purified would bind with the affinity resin. It would have been obvious to a person of ordinary skill in the art to mix the purified sample after elution with the remaining diluent flowing through the column and in the output reservoir or tube 8 as the sample fluid flows through the device during operation.

Hunt teaches that a liquid, which can be interpreted as being the diluent, is provided with the sample in the sample chamber of the purification device that also comprises the bed of particulate separation medium (see paragraph 30). Hunt teaches that the fluid sample to be separated is placed into the purification device through an

entry port, e.g., top opening 24, into the sample chamber 22 of the purification device (see, e.g., paragraph 91). The device is centrifuged to pass the liquid of the sample through the column of the device for purification and the eluate is captured in a collection chamber beneath. Hunt teaches that the flow cross-section through the column bed is substantially smaller that the cross-section of the sample chamber 22 above the column 3 that contains the purification medium (see, e.g., paragraphs 58, 59 and 30; figure 1). The excess diluent solvent in the larger sample chamber would therefore saturate the purification column. Therefore, it would have been obvious to a person of ordinary skill in the art that the purification column would be saturated with diluent or buffer solvent.

Hunt teaches that the sample and diluent can be driven through the purification by centrifugation (see, e.g., paragraph 91). As disclosed in paragraph 91, Hunt does not specifically teach that additional diluent is added during this centrifugation step. Thus, the excess diluent can be driven through the column rendering the purification material free of any excess diluent solvent. The excess diluent and purified sample can be captured in the output reservoir indicated at 82 in the device configuration shown in figure 4. It is obvious to a person of ordinary skill in the art that the purified sample and the removed diluent would be mixed together in the output reservoir.

Furthermore, it would have been obvious to a person of ordinary skill in the art to remove excess diluent from the purification column thereby rendering the purification material free of excess diluent prior to introducing the fluid sample into the purification

column in order to avoid further unnecessary dilution of the final purified sample and to eventually provide a final purified sample solution that is more concentrated.

Regarding claims 2 – 9, Hunt teaches the use of various hydraulic and pneumatic means, such as gravity, pump, vacuum, and including centrifugal or centripetal, for moving diluent and fluid sample through the device (see, e.g., paragraph 94).

Regarding claims 10 and 11, Hunt teaches that the fluid sample can comprise a biological sample, such as nucleic acids or antibodies (see, e.g., paragraph 3).

Regarding claims 12 – 15, Hunt teaches the assembling of the microfluidic device comprising the purification column comprising the purification resin material and diluent or buffer prior to use (see, e.g., paragraphs 57 – 91).

Regarding claims 16 and 17, Hunt teaches the use of size exclusion or gel filtration resin and ion exchange resin (see, e.g., paragraphs 66 and 87).

Regarding claim 18, Hunt teaches that the sample can be processed in a few minutes (see, e.g., paragraph 91). Therefore, it would have been obvious to a person of ordinary skill in the art to contact the fluid sample with the purification material for at least one minute.

Regarding claims 19 – 21, Hunt teaches that the fluid sample can comprise a biological sample, such as nucleic acids (see, e.g., paragraph 3). The use of capillary electrophoresis, polymerase chain reaction and sequencing laboratory techniques with nucleic acids is very well known in the art. Therefore, it would have been obvious to a

person of ordinary skill in the art to incorporate the use of these techniques with a fluid sample comprising nucleic acids in order to facilitate effective sample analysis.

Regarding claim 22, the use of buffers containing chloride ions with ion exchange chromatography media is very well known in the art. Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate the use of a fluid sample including chloride ions with the purification column as claimed in order to preequilibrate the column prior to use or in eluting bound sample from the column to provide a purified fluid sample.

With respect to claim 34, it would have been obvious to scale the column of Hunt down for use with small samples, as for use in microcentrifuge tube.

1. Applicant's arguments with respect to claims 1-23, 34 have been considered but are moot in view of the new ground(s) of rejection.

2. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jan M. Ludlow whose telephone number is (571) 272-1260. The examiner can normally be reached on Monday, Tuesday and Thursday, 11:30 am - 8:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jan M. Ludlow
Primary Examiner
Art Unit 1797

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